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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,416	08/28/2008	Keith Alan Crutcher	81599-004US0	2428

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DAVIS WRIGHT TREMAINE LLP/Los Angeles
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LOS ANGELES, CA 90017-2566

EXAMINER

LUKTON, DAVID

ART UNIT	PAPER NUMBER
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1654

NOTIFICATION DATE	DELIVERY MODE
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12/15/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/586,416	Applicant(s) CRUTCHER, KEITH ALAN	
	Examiner DAVID LUKTON	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-4,6-24,29,31,32,35,36,38 and 39 is/are pending in the application.
- 5a) Of the above claim(s) 16-24,31,32,36 and 39 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-4,6-15,29,35 and 38 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Pursuant to the response filed 10/11/11, claims 1-4, 6-24, 29, 31, 32, 35, 36, 38, 39 are now pending. Claims 1-4, 6-15, 29, 35, 38 are examined in this Office action; claims 16-24, 31, 32, 36, 39 are withdrawn.

Applicant's arguments filed 10/11/11 have been considered and found not persuasive.



Claims 11-13 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is drawn to a method of using a composition. That composition is said to comprise a peptide. A "composition", however, must contain two or more compounds, otherwise it is a compound. Thus, the claim is mandating the presence of a second compound, yet is providing no clues as to what it might be. Is it a carrier? Is it another peptide? Applicants have declined to acknowledge this rejection as it applies to claim 11, and so it is maintained without further comment.



The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 1-4, 6-15, 29, 35, 38 are rejected under 35 U.S.C. §103 as being unpatentable over

Azuma, M. (*Peptides* **21**(3), 327-330, 2000) or Motizuki, Mitsuyoshi (*Biochemical Journal* **342**(1), 215-221, 1999).

As indicated previously, each of the cited references discloses that peptides derived from an apolipoprotein exhibit antibacterial activity.

In response, applicants have asserted that claim 1 imposes certain limitations which, according to applicants, are not met by the reference. However, the claims are nowhere near as constrained as applicants would like to argue.

Consider the language of claim 1:

A method of treating a bacterial infection in a subject, comprising: providing a composition comprising a polypeptide, or a derivative or analogue thereof comprising ... or a derivative thereof... or a derivative thereof.

This may be paraphrased as follows:

A method of treating a bacterial infection in a subject, comprising:

a) providing a peptide of SEQ ID NOS: 1, 2, or 96,

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- b) converting that peptide into a derivative, or into an analog of the derivative,
- c) transforming the analog of the derivative into a derivative of the analog of the derivative, subject to the proviso that the derivative of the analog of the derivative must contain at least two RKR subsequences,
- d) transforming the derivative of the analog of the derivative into a derivative of the derivative of the analog of the derivative; and
- e) administering the derivative of the derivative of the analog of the derivative to the subject.

The examiner can say with absolute certainty that any of the Azuma peptides or the Motizuki peptides qualify as a derivative of a derivative of an analog of a derivative of any of SEQ ID NOS: 1, 2, or 96.

Claim 11 can be justifiably rejected because of the phrase “a truncation thereof”. The peptide of SEQ ID NO:1 can be truncated down to a single amino acid or dipeptide.

The rejection is maintained.

Significant headway would be achieved if all renditions of the terms “analog” and “derivative” were removed from the claims. In the event that either of these terms is retained, the examiner will continue to interpret the claims broadly.

In any case, one option for claim language would be the following (variables P1 and P2 have been created by the examiner here):

A method of treating a bacterial infection comprising administering a composition to a subject in need thereof,

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wherein the composition comprises peptide P1 in combination with a pharmaceutically acceptable vehicle;

wherein peptide P1 comprises a tandem dimer repeat of P2;

wherein P2 is a peptide selected from the group consisting of SEQ ID NOS: 1, 2 and 96; or else P2 is obtained by substituting at least one amino acid of any of SEQ ID NOS: 1, 2 or 96 with an amino acid selected from the group consisting of Arg, Tyr, Met, Ile, Phe and Trp, provided that an amino acid substitution is not made within an RKR motif.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

/David Lukton/

Primary Examiner, Art Unit 1654